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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/022,301 | 12/17/2001 | Lisa McKerracher | 12552-003001/06447-002-US | 1730 |

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EXAMINER

TURNER, SHARON L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,301

Applicant(s)

MCKERRACHER ET AL.

Examiner

Sharon L. Turner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-33 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

Response to Amendment

1. The amendment filed 8-20-04 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of applicant's amendment, all rejections not reiterated herein have been withdrawn by the examiner.
4. The prior art rejections of record are withdrawn as lovastatin and NGF are not compounds of the structures of Y-27632 or the pyridylcarbamoylcyclohexane compounds as newly recited in claims 23-33.

Election/Restrictions

5. Applicant's election without traverse of Group VII in the Paper of 12-9-03 is acknowledged.
6. Claims 1-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Paper of 12-9-03.
7. Claim 22 and new claims 23-33 are pending and under examination.
8. This application contains claims 1-21 drawn to an invention nonelected with traverse in Paper of 12-9-03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Claim Objections

9. Claim 22 is objected to because of the following informalities: "neuronal" is misspelled as 'neural' in claim 22. Appropriate correction is required.
10. Claims 22 and 24 are objected to because of the following informalities: While the prior art compound Y-27632 is recognized in the art, (see US Patent No. 4,799,834), the claim should additionally refer to it via its chemical structure name, i.e., (+)-trans-4-(1-aminoethyl)-1-(4-pyridylcarbamoyl)-cyclohexane 2HCl.1H.sub 2 O. Appropriate correction is required.

Specification

11. The disclosure is objected to because of the following informalities: The views, i.e., (A-C) should be reflected within the figure legends consistent with the figures, see pp. 6-7, for example, "Figure 1A-C shows...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:
- The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
13. Claims 23-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 23-33 are newly presented. Claims 23-33 enjoy support from the specification as outlined within the claims at pp. 9-12 of the amendment filed 8-20-04. However, the citations noted therein does not support the recitations and combinations of elements as newly recited as follows;

Claims 23 is directed to "delivering directly at a traumatic lesion site *in a nerve* in a patient, with noted support at paragraph 118. The recitation "in a nerve" is not apparently supported here in that the administration within the surgical model is via 'application to the spinal cord to allow infiltration of the mixture into the lesion site.', Accordingly the specification supports an extracellular or topical application but not an intracellular application as directed via the recitation 'in a nerve'.

Further, claim 23 recites "in an amount effective to suppress inhibition of neuronal axon growth," with noted support within paragraphs 42 and 52. These citations note 'an amount effective to suppress Rho family member-mediated inhibition of nerve growth' but the claim fails to qualify the inhibition as 'Rho family member mediated' inhibition. The lack of the qualifier as noted in the specification serves to broaden the functional scope of the claim.

Claim 23 newly notes the compound structures as in (i) and (ii) with reference to paragraph 0021 and claim 1 of the '834 patent. While paragraph 21 refers to the '834 patent, the paragraph supports the recitation where "compounds such as Y-27632 (US 4,997,834), that block Rho-associated kinase activity, ... are embodiments of this invention and "the use of other compounds within this family of compounds that inhibit Rho kinase are also considered within the scope of this invention."

However, the specification has not incorporated by reference the scope of the full noted structures of the '834 claim 1 as now recited as those compounds to be incorporated, nor are these compounds noted as those with the activity of the '834 compounds in blocking Rho kinase or Rho-associated kinase as incorporated by the instant specification, but differing from the recitations of the claims. Moreover, the specification fails to specifically note that as intended via the recitation of 'other compounds within this family of compounds that inhibit Rho kinase' either via structure or function (not recited in the claim).

Even further, the claim references that the antagonists bear the functions as in the wherein clauses of claim 23. These paragraphs reference specific data of paragraphs 121, 34, 115 and 116 with respect to Y-27632. While the specification notes such activities with Y-27632, no other compounds or scope of compounds appear to be noted as providing for the noted functional recitations. Moreover, the specification does not apparently support the combination for the selection of antagonists to be used via the noted functional activities of stimulating regenerative growth of damaged neuronal axons past the lesion site and wherein the antagonist has the ability, when triturated into primary retinal ganglion cells in vitro to produce outgrowth of retinal ganglion cell neurites, the retinal ganglion cells being plated on a growth inhibitory substrate selected from the group consisting of myelin and chondroitin sulfate proteoglycan' as now claimed.

Accordingly, these recitations and their newly recited combination are not apparently supported from the original specification as now claimed. Applicant's

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traversal should note reference to the specification as originally filed (not to the published document) where direct support for the recitations and combinations is evidenced.

Status of Claims

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Conclusion

16. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

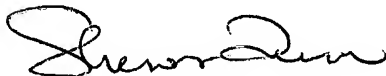
Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should

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applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at (571) 272-0961.



Sharon L. Turner, Ph.D.
November 12, 2004

SHARON L. TURNER, PH.D.
PATENT EXAMINER